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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,920	01/25/2006	Sanjay E. Rastogi	4662-124	2936
23117 7590 09/07/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER CHOI, LING SIU	
			ART UNIT 1713	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/561,920	Applicant(s) RASTOGI ET AL.	
	Examiner Ling-Siu Choi	Art Unit 1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/10/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Claims 1-14 are now pending, wherein claims 1-11 are drawn to a process; claim 12 is drawn to shaped part; claims 13-14 are drawn to a use of a shaped part. Claim 1 is an independent one.

#### ***Specification***

2. The disclosure is objected to because of the following informalities: a paragraph under the heading of "Brief Description of the Drawings" to describe drawings is missing.

Appropriate correction is required.

#### ***Claim Objections***

3. Claim 2 is objected to because of the following informalities: (a) claim 2, line 1, "Θ" is suggested to be changed to --a heating rate Θ-- and (b) claim 8, line 4, "1\*10<sup>-4</sup> mol/L" is suggested to be changed to --1 x 10<sup>-4</sup> mol/L--.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

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## 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3, lines 1-2, claim 3 depends on claim 2, wherein a heating rate is at most 1 k/min. Thus, the heating rate cited in claim 3 can not be higher than 1 K/min.

***Claim Analysis***

## 6. Summary of Claim 1:

Process to prepare a shaped part of an ultrahigh molecular weight polyethylene (UHMWPE)	
<ul style="list-style-type: none"><li>- heating the UHMWPE to a temperature above the melting temperature,</li><li>- shaping the resulting melt, and</li><li>- cooling the melt to a temperature below the melting temperature, wherein</li></ul>	
A	the UHMWPE has a weight average molecular weight (Mw) of at least $1 \times 10^6$ g/mol
B	during the shaping the storage plateau modulus ( $G^*$ ) of the UHMWPE is kept at a value of at most 1.5 MPa
C	whereafter, before the cooling, the $G^*$ is raised to its final value

***Claim Rejections - 35 USC***

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7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Claim Rejections - 35 USC § 102***

Claims 12-14 are drawn to a product-by-process claims. The caselaw has held that "[t]he patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698,227 USPQ 964, 966 (Fed. Cir. 1985). The claimed G\* value during the shaping step is part of process. Thus, it would not carry any patentable weight until it is shown to have effect on the shaped article so produced.

9. Claims 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Burstein et al. (US 5,721,334).

Burstein et al. disclose a shaped article and a medical device, which is prepared by the process comprising (a) filling a mold with powdered ultra high molecular weight polyethylene; (b) raising the temperature of the mold to between about 140-225°C while simultaneously applying a pressure of between about 2.5 -15 MPa to the mold and its contents; (c) maintaining the pressure and temperature for between about 5 -25 min to allow the mold contents to equilibrate at the selected temperature; and (d) dropping the temperature of the molded part at a rate between about 4 -175°C./min by contact with a suitable cooling fluid such as water or air, wherein the ultra high molecular weight polyethylene (UHMWPE) has an average molecular weight of between about  $1 \times 10^6$  and about  $10 \times 10^6$  and the shaped articles are used in the bearing surface of total knee joints, prosthetic hip joint cups, and other prosthetic shapes for replacement of other joints of the human body (abstract; claim 1). Thus, the present claims are anticipated by the disclosure of Burstein et al.

10. Claims 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rastogi et al. (US 6,433,120 B1).

Rastogi et al. disclose a shaped article and a biomedical device obtained by a process to process ultra-high molecular weight polyethylene (UHMWPE - Hostalen GUR 4130)) having a molecular weight (Mw) of at least 400,000, the process comprising (a) providing UHMWPE particles having a lamellar thickness of <12 nm and a melting temperature at atmospheric pressure >141° C; (b) heating the particles from ambient temperature under an elevated pressure of at least 0.5 kbar in a pressure cell;

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(c) continuing the heating of the resulting UHMWPE under an elevated pressure to at least the melting temperature of the UHMWPE; (d) cooling the resulting melted UHMWPE product to ambient temperature; and (e) removing the cooled product from the pressure cell, wherein the speed of heating in step (c) is 0.5-5°C./min (claim 1 and 13). Thus, the present claims are anticipated by the disclosure of Rastogi et al.

***Claim Rejections - 35 USC § 102/103***

11. Claims 1-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burstein et al. (US 5,721,334).

Burstein et al. disclose a process to make a shaped article, the process comprising (a) filling a mold with powdered ultra high molecular weight polyethylene; (b) raising the temperature of the mold to between about 140-225°C while simultaneously applying a pressure of between about 2.5 -15 MPa to the mold and its contents; (c) maintaining the pressure and temperature for between about 5 -25 min to allow the mold contents to equilibrate at the selected temperature; and (d) dropping the temperature of the molded part at a rate between about 4 -175°C./min by contact with a suitable cooling fluid such as water or air, wherein the ultra high molecular weight polyethylene (UHMWPE) has an average molecular weight of between about 1 x 10<sup>6</sup> and about 10 x 10<sup>6</sup>; the shaped article so produced exhibits a combination of properties including an elastic modulus between about 500- 800 MPa, a yield strength ≥ about 20 MPa, an elongation to rupture > about 300%, crystallinity and density ≤ the native

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powdered UHMWPE; and the shaped articles are used in the bearing surface of total knee joints, prosthetic hip joint cups, and other prosthetic shapes for replacement of other joints of the human body (abstract; claim 1). However, Burstein et al. are silent on the specific properties in the shaping stage. In view of the process and the UHMWPE being substantially identical to the corresponding ones of the present claims, the shaped article would possess the claimed properties of the shaping stage because such claimed properties mainly depend on the molecular weight of UHMWPE and the processing conditions. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald* 205 USPQ 594 (CCPA 1980).

12. Claims 1-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rastogi et al. (US 6,433,120 B1).

Rastogi et al. disclose a process to process ultra-high molecular weight polyethylene (UHMWPE) having a molecular weight (Mw) of at least 400,000, the process comprising (a) providing UHMWPE particles having a lamellar thickness of <12 nm and a melting temperature at atmospheric pressure >141° C; (b) heating the particles from ambient temperature under an elevated pressure of at least 0.5 kbar in a pressure cell; (c) continuing the heating of the resulting UHMWPE under an elevated pressure to at least the melting temperature of the UHMWPE; (d) cooling the resulting melted UHMWPE product to ambient temperature; and (e) removing the cooled product from the pressure cell, wherein the speed of heating in step (c) is 0.5-5°C./min (claim 1



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and 13). However, Rastogi et al. are silent on the specific properties in the shaping stage. In view of the process and the UHMWPE being substantially identical to the corresponding ones of the present claims, the shaped article would possess the claimed properties of the shaping stage because such claimed properties mainly depend on the molecular weight of UHMWPE and the processing conditions. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald* 205 USPQ 594 (CCPA 1980).

### **Conclusion**

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ling-Siu Choi whose telephone number is 571-272-1098.

If attempt to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu, can be reached on 571-272-1114.

  
LING-SUI CHOI  
PRIMARY EXAMINER

August 25, 2007